AMERICAN SOCIETY OF HEMATOLOGY
2021 L Street, NW, Suite 900, Washington, DC 20036-4929 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

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2024
President
Mohandas Narla, DSc
New York Blood Center Enterprises
310 E 67th Street
New York, NY 10065
Phone 212-570-3056

President-Elect
Belinda Avalos, MD
Atrium Health Levine Cancer Institute
1021 Morehead Medical Drive
Building I, Suite 3000
Charlotte, NC 28204
Phone 980-442-2000

Vice President
Robert Negrin, MD
Stanford University
CCSR Building, Room 2205
269 W. Campus Drive
Stanford, CA 94305
Phone 650-723-0822

Secretary
Cynthia Dunbar, MD
NHLBI/NIH
Translational Stem Cell Biology Branch
Building 10-CRC, Room 5E-3332
10 Center Drive
Bethesda, MD 20892
Phone 301-402-1363

Treasurer
Joseph Mikhael, MD, FRCPC, MEd
Translational Genomics Research Institute
City of Hope Cancer Center
445 N. Fifth Street
Phoenix, AZ 85004
Phone 602-343-8445

Councillors
Christopher Flowers, MD, MS
H. Leighton Grimes, PhD
Mary Horowitz, MD
Charlotte Niemeyer, MD
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Betty Pace, MD
Jamile Shammo, MD
Wendy Stock, MD, MA

Executive Director
Martha Liggett, Esq.

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Submitted via email to: *NIHReform@mail.house.gov*

Dear Chair McMorris Rodgers:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments on your framework to reform the National Institutes of Health (NIH). We recognize that the Agency has been operating under an expired authorization; a robust reauthorization process will provide an opportunity for the Energy and Commerce Committee, the Senate Health, Education, Labor and Pensions (HELP) Committee, and stakeholders to ensure that NIH continues to be the preeminent biomedical research institution in the world.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical (non-malignant) conditions such as sickle cell disease (SCD), thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

Our mission is to foster high-quality, equitable care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders. NIH has played an important role in supporting transformative research in hematology, a key part of that mission. As an example, NIH investments have led to the development of cutting-edge therapies in the field of hematology including gene therapies for SCD and chimeric antigen receptor (CAR) T-cell therapies for certain blood cancers. As such, ASH is committed to ensuring that NIH continues to invest in basic and translational science to improve human health.

ASH welcomes the opportunity to work with you and other members of the Energy and Commerce Committee to engage in a thorough review and reauthorization of NIH. However, we are concerned that the framework that has been released was developed without the input of a wide range of stakeholders, including the NIH. To reauthorize a $48 billion agency, the committee should not only work closely with NIH leadership, but also specialty societies, like ASH, patient groups, research institutions, and other stakeholders. Therefore, we encourage you to engage in a bipartisan and bicameral process with hearings and multiple opportunities for stakeholder feedback to support a thorough and well-considered reauthorization.

Additionally, ASH would like to provide the following comments on the specific policies in the NIH reform framework:

Proposal to Collapse the 27 Institutes and Centers into 15

Like the Committee, ASH is concerned about research silos at NIH. There are many cross-cutting research issues that would benefit from better coordination and collaboration across the institutes and centers. However, we are concerned that the proposal to combine institutes may not have the intended effect.

A number of institutes and centers at NIH have unique hematology research portfolios, including the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National cancer Institute (NCI), and the National Institute on Aging (NIA). Combining NHLBI and NIDDK with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) into a new National Institute on Body Systems Research poses a number of issues for the hematology community. With such a large institute, there is the potential for more specialized research areas to be overlooked, particularly if the expertise at the program officer level is not maintained. Furthermore, the proposed restructuring could have significant implications on how research on rare diseases is prioritized and funded. Most hematologic diseases fall under the rare disease category because they impact fewer than 200,000 people living in the United States; to that end, it is critical that careful consideration be given to how research on rare diseases will be effectively supported if the institutes are combined. Of note, the current NIH structure ensures that there is a comprehensive set of directives and clear focus on diseases like sickle cell disease, thalassemia, and aplastic anemia, that only affect a comparatively small population of individuals in the United States. While each of these diseases – and many others – affect a comparatively small population of individuals in the U.S., the impact on the patients with these diseases can be catastrophic and the combined impact of these diseases on Americans is profound. Restructuring and combining institutes in pursuit of efficiencies in administration may mean we lose the opportunity to create new treatments for these and other rare diseases and disorders. Also, NIH supports most pre-clinical research, so if there is any reduction in this investment because of the consolidation, it will slow the pace of development of novel therapies, which have already transformed the practice of hematology.

Instead of collapsing the institutes, ASH recommends that the committee consider other methods to break down the existing silos. For cross-cutting research topics, NIH and its institutes and centers could be required to create interdisciplinary teams. These teams should be charged with supporting meetings and workshops on cross-cutting research areas. By convening NIH representatives and researchers regularly, they will be encouraged to share new ideas and develop partnerships. This can lay the foundation for more joint funding opportunities. The U-mechanism is already being used with some success to support interdisciplinary science. Further investment in existing grant mechanisms and the development of new mechanisms could foster greater collaboration. Additionally, requirements for open data and resource sharing will further enhance collaboration. The NIH has already begun moving in this direction, but ASH recommends that efforts be taken to ensure that institutes, centers, and research grantees are sharing resources through formal requirements and agreements.

Furthermore, the committee should consider requiring NIH's research to be informed by a more diverse set of stakeholders. Patients and their communities may be overlooked in the existing biomedical research enterprise. However, they are the end users of the biomedical research supported by NIH. They should be involved in the research process, potentially through workshops, to foster research that addresses real world needs and improves health outcomes. Another way to break down

silos and foster innovation is to support more public-private partnerships, which may help support faster translation of research findings into practical applications and treatments.

Term Limits for Institute and Center Directors
ASH understands the committee's motivation for proposing term limits for institute and center leaders and shares the goal of ensuring that leadership is not stagnant. However, ASH believes that there is a benefit to continuity in leadership, particularly in biomedical research where it takes time to meet certain scientific goals. Instead of limiting directors to two five-year terms, we recommend that institute and center directors serve five-year terms that continue to be subject to review without placing a term limit on their tenure.

Indirect Costs
The committee's framework considers indirect costs, which cover overhead expenses at research institutions, and alternative mechanisms to limit them and increase transparency by requiring the entities receiving grant awards to report their costs publicly. ASH appreciates the committee's interest in this topic. Our goal is for as much of the federal investment in NIH to support new biomedical research as possible; and therefore, we believe that the policies around indirect costs deserve more scrutiny and potentially greater transparency. We encourage this topic to be included in a robust discussion around NIH's reauthorization.

Grant Awards
ASH appreciates the committee's interest in ensuring that grant recipients remain dynamic and supporting the entry of new investigators into the biomedical research pathway. These are topics that deserve careful consideration during a robust reauthorization process. While, on its face, it may seem reasonable to cap the number of awards on which a grantee can serve as a primary investigator at three, there may be unintended consequences of this policy. Primary investigators have grants with different start and end dates and may have to apply for more grants to cover gaps to allow them to continue important research. Losing grant money may be particularly detrimental for physician-scientists who must apply for new grants to support the protected time away from patient care needed to conduct research. In addition, there are many different types of funding mechanisms, and limiting the number of awards on which investigators can serve as the primary investigator may cause researchers to focus on their individual lab's work and stifle important collaborations, training programs, and interdisciplinary research projects. These concerns must be balanced with policies that support early-stage investigators' introduction into the biomedical research enterprise. ASH remains concerned about the future of hematology researchers, but particularly at risk is the physician-scientist workforce, and NIH must have policies that support research as a viable career for them.

Thank you for the opportunity to provide comments on this draft framework. We look forward to working with you to support a robust reauthorization process for NIH. Should you have any questions, please contact Tracy Roades, ASH Senior Manager, Legislative Advocacy, at troades@hematology.org or 202-776-0544.

Sincerely,

Mohandas Narla, DSC
President